

REMARKS

Claims 21-58 have been rejected by the Examiner under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. Specifically, the Examiner has stated that the terminology "second hollow container" is unclear. In response thereto, the Applicants have amended independent claims 21, 31, 42, 48 and 54 as recommended by the Examiner to overcome the rejection under 35 USC 112, second paragraph.

In addition, claim 36 has been amended to add a part of the claim inadvertently omitted. No new matter is added by the present amendment.

Claims 21-56 have been rejected by the Examiner under 35 USC 103(a) as being unpatentable over WO 97/25606 to Rasmussen, et al. in view of U.S. 6,164,144 to Berg.

In this rejection, the Examiner has stated that Rasmussen, et al. teaches a device and method for liquid-liquid micro-extraction and the method comprises providing a carrier, modifying the carrier, immobilizing a solvent on the carrier surface, contacting the carrier with the sample, concentrating and fixing the analyte of interest to the solvent and analyzing the carrier. The Examiner also states that Rasmussen teaches a fiber carrier.

However, the Examiner acknowledges that Rasmussen, et al. does not specifically teach the use of a hollow fiber

or an acidified acceptor solution. The Examiner states that Berg teaches methods and device for a solid phase micro-extraction (SPME). The reference teaches the use of a hollow fiber with SPME wherein the fiber access a "sponge". In addition, the reference also teaches the use of a magnetic stirring bar as the means of agitation of the sample in the vial.

The Examiner concludes it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use a magnetic stirring bar, hollow fiber, and an acidified acceptor solution with the invention of Rasmussen, et al.

The Examiner has agreed that neither Rasmussen or Berg teach LLME or LLLME where the analyte passes through the membrane wall and is collected on an opposite side. However, the Examiner has maintained that such arrangement would have been obvious to one of ordinary skill in the art at the time the invention was made.

As earlier pointed out by the Applicants, each of the references is related to structure and method for a separation of an analyte using a surface phenomenon. As claimed, the present invention includes a second container, that is hollow, which includes a membrane wall with fiber pores permeable by the analyte and means for enhancing transport of the analyte from the sample through the membrane wall and into the acceptor solution.

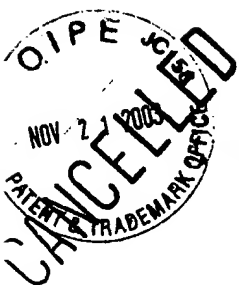
This must be contrasted with the surface phenomenon of the Rasmussen, et al. and Berg references. In fact, it has

been held that a surface does not constitute a layer with interconnected pores and that such a surface would not lead a person of ordinary skill in the art to the use of a membrane wall with fiber pores. See American Standard, Inc. v. Pfizer, Inc., 14 USPQ 2d 1673, 1713 (Dist. Ct. D. Del. 1989) (copy enclosed).

The Applicants submit that a prima facie case has not been made by the Examiner. The Examiner has failed to adequately explain why the skill routineer in this art would have been motivated to use the hollow porous fiber claimed in the present application. Ortho Kinetics, Inc. v. Safety Travel Chairs, Inc., 1 USPQ 2d 1081 (Fed. Cir. 1986).

The Examiner has present no supporting explanation or evidence why it would have been obvious to use the particular hollow porous membrane presently claimed. Ex parte Marinaccio, 10 USPQ 2d 1716, 1717 (PTO Bd. Pat. App. Int. 1989). (Copy enclosed)

The Applicants further submit that the Examiner is basically relying on general knowledge to negate patentability on the ground of obviousness and this necessitates an articulation of that knowledge in order to place it on record since Examiners are presumed to act from the view point of persons of ordinary skill in the art in finding relevant facts accessing significance of prior art and making ultimate determination of obviousness issue. A failure to do so is not consistent with either effective administration, procedure or effective judicial review and accordingly conclusionary statements when dealing with



3013

particular combinations of the prior art and specific claims must set forth the rational on which it relies. In re Lee, 61 USPQ 2d 1430, 1435 (CAFC 2002).



In conclusion, in view of the arguments hereinabove set forth, the Applicants submit that a prima facie case of obviousness has not been made in the rejection of claims 21-58 under 35 USC 103(a) on the basis of the Rasmussen, et al. and Berg references.

In view of the arguments hereinabove set forth and amendment to the claims, it is submitted that each of the claims now in the application define patentable subject matter not anticipated by the art of record and not obvious to one skilled in this field who is aware of the references of record. Reconsideration and allowance are respectively requested.

Respectfully submitted,

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plaintiffs' prima facie showing of their ownership in the copyright. Thus, the plaintiffs have not satisfied their burden of establishing their likelihood of success on the merits of their copyright claim. Accordingly, this Court must deny plaintiffs' motion for injunctive relief.

**Patent and Trademark Office
Board of Patent Appeals and Interferences**

Ex parte Marinaccio

No. 86-1462

Released March 9, 1989

PATENTS

1. Patentability/Validity — Obviousness — Person of ordinary skill in art (§115.0902)

Patentability/Validity — Obviousness — Combining references (§115.0905)

Examiner's rejection of appealed claims for cross-flow filtration process on grounds that claims are obvious in view of three prior references in combination is reversed, since examiner has failed adequately to explain why skilled routineer would use filter medium of claims which was specifically noted by primary reference to be unacceptably prone to clogging, since no reference or combination of references appears to teach or suggest use of specific type of filter membrane required by appealed claims, and since, although skilled routineer could no doubt modify prior art relied on by examiner to obtain appealed process, proper question under 35 USC 103 is what would have "been obvious" for such person to do.

Appeal from rejection of claims (Frank Spear, primary examiner).

Patent application of Paul J. Marinaccio and Ronald V. Repetti, serial no. 566,839, filed Dec. 29, 1983. From examiner's rejection of all claims in application, applicants appeal rejection of claims 1-33. Reversed.

Michael E. Zall, of Weingram & Zall, Maywood, N.J., for appellants.

Before Winters, Downey and Metz,
examiners-in-chief.

Metz, examiner-in-chief.

This is an appeal from the examiner's refusal to allow claims 1 through 35, all the claims in the application. At Oral Hearing, appellants' representative indicated that there was an amendment filed on even date with appellants' Brief requesting cancellation of claims 34 and 35. Our review of the record indicates that the paper is included in the application papers, however, it has not been entered in the contents of the application. When asked if it was appellants' intention to pursue an appeal of claims 34 and 35, appellants' representative indicated that appellants no longer intended to appeal from the examiner's decision with respect to claims 34 and 35 and, accordingly, we take appellants' representative's representation as a withdrawal of the appeal of claims 34 and 35. Accordingly, the only claims before us for our consideration in this appeal are claims 1 through 33.

The appealed subject matter is directed to a process for the cross-flow filtration of a liquid containing particulates or suspended solids and dissolved solids. The process comprises circulating the liquid containing said particulates or suspended solids and dissolved solids tangential to and axially on one side of a charge modified organic polymeric skinless microporous hollow fiber filter membrane. Claim 1, the only independent claim before us for our consideration, is reproduced below for a more facile understanding of appellants' invention:

"A process for the cross-flow filtration of a liquid containing particulate or suspended solid and dissolved solids comprising circulating the liquid tangential to and axially on one side of a charge modified organic polymeric skinless microporous hollow fiber filter membrane, substantially retaining the particulate or suspended solids on said one side, the dissolved solids passing through the membrane and the charge on the membrane repelling similarly charged particulate or suspended particles preventing clogging or blocking of pores through excessive adsorption of said particulate or suspended solids.

The references of record which are being relied upon by the examiner as evidence of obviousness are:

Gregor	3,808,305	Apr. 30, 1974
Klein et al. (Klein)	4,051,300	Sep. 27, 1977
Dorson et al. (Dorson)	WO 82/03568	Oct. 28, 1982

The appealed claims stand rejected as being unpatentable under 35 U.S.C. 103 from Dorson taken with Klein and Gregor. We reverse.

In any rejection founded upon 35 U.S.C. 103, the scope and content of the prior art must be determined, the differences between the prior art and the claims in issue must be ascertained and, finally, the level of ordinary skill in the relevant art must be resolved. *Graham v. John Deere*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). In determining the scope and content of the prior art it is appropriate for us to consider that which is admitted by appellants to be old in the art. *In re Nomiya*, 509 F.2d 566, 184 U.S.P.Q. 607 (CCPA 1975). Accordingly, we note that appellants have conceded that cross-flow filtration methods are well known in the art (page 6, first full paragraph of appellants' Brief) and that the charge modified organic polymeric microporous membranes are, *per se*, known (page 6, second paragraph of appellants' Brief). It is this background against which we must determine the propriety of the examiner's rejection.

Essentially, while appellants recognize that Dorson describes a filtration process which utilizes cross-flow circulation of the fluid being filtered, it is appellants' position that Dorson is directed to a type of filtration, that is ultra filtration, which is so distinct from the type of filtration claimed by appellants that Dorson may not be relied upon to reject the appealed claims. Appellants also maintain that Dorson utilizes flat stock asymmetric skinned membranes and not charge modified organic polymeric skinless microporous hollow fiber filter membranes as required by the appealed process. Appellants submit that the only reference in Dorson to hollow fibers is the disclosure at page 13 of the reference which states that rapid plugging of a substantial number of fibers can occur and unacceptably diminish the affected area of the filter for Dorson's purpose. Appellants strongly urge that such a disclosure would direct the skilled routineer in this art away from the use of hollow fibers rather than teaching their usefulness. Since the secondary references are not directed to convective or cross-flow filtration of the type claimed but are directed to ultra filtration and reverse osmosis processes, appellants urge that the references are not properly combinable with the Dorson reference. Further, it is appellant's position that the secondary references do not describe the specific type of filter membrane required by the appealed claims nor do they suggest any modification of the Dorson filter material

which would suggest or render obvious the particular membrane utilized by appellants in their process.

The examiner has failed to challenge or argue against appellants' distinctions between the type of filtration claimed and the filtration processes described in the prior art relied upon. Rather, the examiner has taken the apparent approach that because Dorson describes a filtration process which utilizes cross-flow circulation of the medium being filtered that the use of any filtration medium in said process would have been obvious regardless of Dorson's specific disclosure against the use of hollow fibers. We are satisfied, however, that based upon appellants' positively recited claim limitations, the description of the term "cross-flow filtration" found at page 32, lines 14 through 23 of appellants' specification and the distinctions drawn between the various types of filtration (batch filtration, ultra filtration and reverse osmosis) that the modification and substitutions proposed by the examiner and based upon the prior art of record would not have been obvious to one of ordinary skill in this art at the time appellants' invention was made.

[1] As we noted above, the examiner has failed to adequately explain why the skilled routineer in this art would have been motivated to use a particular filter medium specifically noted by Dorson as being unacceptably prone to clogging. We note, too, that no reference or combination of references appears to teach or suggest a specific charge modified organic polymeric skinless microporous hollow fiber filter membrane required by the appealed claims. While we have no doubt that the skilled routineer in this art could modify the prior art relied upon by the examiner and obtain the appealed process, the question of obviousness under 35 U.S.C. 103 is not what a routineer could have done but what it would have "been obvious" for such a person to do. *Ortho Kinetics Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1 U.S.P.Q. 2d 1081 (Fed. Cir. 1986). The examiner has presented no supporting explanation or evidence why it would have been obvious to use the particular membranes of the appealed claims in appellants' particular type of filtration process.

The decision of the examiner is reversed.
REVERSED.

for the District of Kansas. In an initial decision of May 6, 1988, the district court dismissed the suit for lack of jurisdiction. *Stagner v. United States Patent and Trademark Office*, 8 USPQ2d 1173 (D. Kan. 1988). Since Mr. Stagner failed to exhaust his administrative remedies, the district court determined it had no jurisdiction.

However, on reconsideration, the district court determined that it had jurisdiction over Stagner's due process claim based on 28 U.S.C. §1338, covering all actions arising under the patent laws, and 28 U.S.C. §1361 covering actions for mandamus.

In its reconsideration decision, the district court granted summary judgment against Stagner in the three consolidated cases. *Stagner v. United States Patent and Trademark Office*, 11 USPQ2d 1553 (D. Kan. 1989). The present appeal, which is from that decision, was transferred to this court from the Tenth Circuit.

We agree with the district court's determination that "the plaintiff has failed to allege any instances in which the patent procedure denied him due process, or any situation in which the Commissioner acted arbitrarily, capriciously, or contrary to law." See *Celotex Corp. v. Cairetti*, 477 U.S. 317 (1986). Mr. Stagner has failed to establish any ground for reversing the court's decision and we find none.

Mr. Stagner argues that the district court, "wrongly construed the complaints and the amended complaints filed by the plaintiff-appellant against the defendants-appellees into a merit issue from a clear procedure issue." However, as the district court correctly observed in its decision of May 6, 1988, "the gist of plaintiff's complaint is that he was unlawfully deprived of the issuance of a patent and wishes this court to review the denial." Moreover, a review of appellant's amended complaint shows that his basic contention is that the PTO examiner wrongfully and erroneously rejected his applications for a patent. Thus, Mr. Stagner's dispute with the examiner's grounds for rejection are disputes on the merits of his applications. Although Mr. Stagner's suits in the district court were premature, the thorough and well-reasoned opinions of that court show that he was accorded all the rights to which he was entitled as a pro se plaintiff.

Finally, we note that our decision in this appeal does not leave Mr. Stagner without a remedy. His fourth patent application is still pending in the PTO. If it is finally rejected by the examiner, he can appeal within the PTO and if dissatisfied with that decision, he can seek judicial review pursuant to either 35 U.S.C. §141 or §145.

District Court, D. Delaware

REMEDIES

5. Monetary — Damages — Patents — Increased damages (§115.0507.07)

Letter opinion from outside patent counsel is insufficient by itself to prove good faith belief that patent in suit is invalid, but rather all evidence must be evaluated to ensure that such opinion does not represent attempt to circumvent consequences of deliberate patent infringement; totality of circumstances demonstrating that defendants, even though they were aware of claimed device and knew that their product fell within scope of claims, had good faith basis for believing that claims were invalid warrants finding that infringement was not willful.

PATENTS

6. Patentability/Validity — Date of invention — Diligence (§115.0409)

Delay of two and one-half months in completing spray coating of test specimens is not prima facie unreasonable or significant evidence that inventor did not act diligently in reducing invention to practice, even though no reasonable explanation was offered for such delay, since imposition of such temporal restrictions on inventors in their studied approach to experimentation would be not only burdensome but foolhardy, and could frustrate, and in many situations defeat, goals of fostering inventive spirit.

7. Patentability/Validity — Date of invention — Diligence (§115.0409)

Inventor may rely on activities directed toward raising capital or funding in order to prove due diligence in reducing invention to practice.

8. Patentability/Validity — Date of invention — Diligence (§115.0409)

General assertions of diligence, without corroboration, are insufficient to permit defendants to meet their burden of proof.

9. Patentability/Validity — Obviousness — Relevant prior art (§115.0903)

Scope and content of prior art for prosthetic bone implants include fields of prosthetic devices and suitable materials for orthopedic, dental, and cardiovascular implants.

10. Patentability/Validity — Obviousness — Person of ordinary skill in art (§115.0902)

Obviousness inquiry under 35 USC 103 is directed toward hypothetical person of ordinary skill in art, and not toward inventor's

American Standard Inc. v. Pfizer Inc.

No. 83-834 LON

Decided October 10, 1989

PATENTS

1. Patent construction — Claims — Defining terms (§125.1305)

Term "bone implant," as used in claims for prosthetic bone implant, has accepted meaning within orthopedic community as referring to manufactured devices that are intended to be placed in human body against or within bone itself, and term must be interpreted to refer generally to prosthetic devices used for implantation, and thus patent claims are not limited solely to porous coated implants manufactured and sold only for adhesion by bone ingrowth.

2. Infringement — Defenses — In general (§120.1101)

Exemption from infringement liability provided under 35 USC 271(e)(1) applies not only to investigative use of patented drugs but also to investigative use of "medical devices," but such exemption does not apply to defendants' "investigational" use of medical prosthesis product that was same as product designed for sale, since investigational product was not used solely for purpose of submitting information to Food and Drug Administration.

3. Infringement — Defenses — In general (§120.1101)

Defendants cannot shield themselves from infringement liability merely by affixing, to their medical prosthesis bone implants, label admonishing surgeon to use device only in non-infringing manner with bone cement, when device is equally capable of being used in infringing manner without bone cement.

4. Infringement — Doctrine of equivalents — Reverse equivalents (§120.0703)

Accused prosthetic bone implant device that reflects use of technological changes to create optimum conditions for achieving bone fixation, but that does not perform function of fixation in substantially different way than claimed device, has not been shown to be non-infringing under reverse doctrine of equivalents.

cost and Henry Hahn as teaching the way to apply a porous metal coating. In fact, the publication deals only with the flame spraying of ceramic coatings on metal and there is no mention in that article of flame spraying of a metal coating on a metal surface. PX-17; D.I. 340, Vol. I at 2753-54; PX-28, col. 4, lines 6-9.³¹ In relying on references to plasma flame ceramic coating to teach his metal flame spray coatings, Hahn acknowledged what the Court has concluded; that is, it was well known in 1968-1969 that ceramics and metals were interchangeable for applying a porous coating to a metal substrate. Consequently, evidence of the interchangeability of a porous metal coating with a porous ceramic coating is a strong indicia of obviousness. See, e.g., *In re Dow Chemical Co.*, 837 F.2d 469, 473 [5 USPQ2d 1529, 1531-32] (Fed. Cir. 1988); *In re Merck & Co.*, 800 F.2d 1091, 1097 [231 USPQ 375, 379-80] (Fed. Cir. 1986).³²

Plaintiff's only response is that Dr. Hulbert's work with ceramics taught away from the concept of using a porous metal coating on a solid metal substrate. In support of this argument, Plaintiff cites to Dr. Hulbert's testimony on cross-examination that "there is no suggestion in any of those [prior art publications] to use a porous metal coating on a solid metal substrate." D.I. 340, Vol. I

³¹ The publications' disclosure of a the technique for flame spraying ceramics entails the same technology for flame spraying metals. D.I. 340, Vol. I at 2754; PX-17; PX-28, col. 4, lines 6-9.
³² Since the mere "substitution of a new material (e.g., metal instead of ceramics) in an old formulation (e.g., plasma flame spraying) generally does not amount to [an] invention," *Friction Div. Products*, 693 F.Supp. at 130 [8 USPQ2d at 1666], it is not unreasonable to conclude that Dr. Hulbert's work would be obvious to one of ordinary skill. For example, in *Egley v. United States*, 376 F.2d 309, 317 [195 USPQ 68, 75] (Ct.Cl. 1978), the court held:

The combination, as a whole, that results from the addition of an old element in corresponding positions of interchangeable devices, especially where the addition produces only the function it is known to perform and no new or unexpected function, has long been held to be obvious within the meaning of 35 U.S.C. §103. See *Ellicott Machine Corp. v. United States*, 186 Ct.Cl. 655, 667, 405 F.2d 1385, 1391 [157 USPQ 149, 154] (1969).

³³ *In re Fout*, 675 F.2d 297, 301 [213 USPQ 2, 536] (C.C.P.A. 1982); *Brunswick Corp. v. Champion Spark Plug Co.*, 689 F.2d 740, 750 [16 USPQ 1, 10] (7th Cir. 1982); *Application of Benitrit*, 372 F.2d 566, 568 [152 USPQ 618, 91] (C.C.P.A. 1967); *AMP Incorporated v. Rindy Corporation*, 332 F.2d 236, 239 [141 USPQ 705, 707] (3rd Cir. 1964).

promote bone ingrowth. Moreover, Defendants failed to offer any evidence that one of ordinary skill in the art would have found the claims of the '123 Patent obvious upon reading the Cohen article. Since a rough surface does not constitute a separate and distinct layer with interconnected pores, it fails to read on the claims of the '123 Patent and would not have led the person of ordinary skill in the art to the invention.

Similarly, the Haboush Patent fails to render the claims of the '123 Patent obvious because it only teaches the use of recesses or grooves on an acetabular cup component of a hip prosthesis. DX-499; D.I. 340, Vol. Q at 3812. These grooves do not constitute a porous metal layer applied to the substrate. In addition, the patent does not disclose the interconnection of pores and does not require the growth of bone tissue into the grooves so as to achieve fixation because the Haboush Patent advocates the use of bone cement to achieve fixation. DX-499, col. 4, lines 18-19. Although the Haboush Patent, like the Austin Moore prosthesis, indicates the direction scientists were taking in the 1950's toward developing a bone implant which could achieve fixation by means of bone ingrowth into pores, it fails to suggest that such a method could be achieved by applying a porous metal layer to a metal substrate. In addition, Defendants did not introduce any evidence at trial that one of ordinary skill in the art would have found the claims of the '123 Patent obvious based upon the disclosure in the Haboush Patent. Thus, the Haboush Patent fails to render the claims of the '123 Patent obvious under Section 103.

Finally, the Ashuckian and Friel dental implants fail to render the claims of the '123 Patent obvious because neither reference teaches the application of a porous metal layer on the implant so as to achieve fixation through bone ingrowth. DX-24; DX-496. Instead, the Ashuckian Patent discloses deep impressions or holes in the wall of a dental implant to permit the expansion of the root so as to prevent movement of the implant. DX-24, col. 1, line 6-70. The Friel Patent only discloses holes or fenestrations in a dental implant. Although these references indicate that it was well known that bone tissue could grow into pores so as to achieve fixation of the artificial tooth, neither reference discloses a separate porous layer applied to a metal base. The Defendants also failed to introduce any evidence that one of ordinary skill in the art would have found the claims of the '123 Patent obvious based upon the disclosure in these two patents. Thus, the Court concludes that the Ashuckian and

Friel Patents cannot render the claims of the '123 Patent obvious.

D. Secondary Considerations

As noted, *supra*, "evidence of secondary considerations may often be the most probative and cogent evidence in the record." *Stratoflex*, 713 F.2d at 1538 [218 USPQ at 879]; see also *Phillips*, 673 F.Supp. at 1317 [6 USPQ2d at 1095]. But a "nexus between the merits of the claimed invention and the evidence of secondary considerations is required in order for the evidence to be given substantial significance in an obviousness decision." *Simmons Fastener Corp. v. Illinois Tool Works*, 739 F.2d 1573, 1575 [222 USPQ 744, 746] (Fed. Cir. 1984). Thus, objective evidence of secondary consideration is to be "carefully appraised in relation to the facts of the actual case in which it is offered." *Cable Elec.*, 770 F.2d at 1026 [226 USPQ at 887]; *EWB Corp.*, 755 F.2d at 905 [225 USPQ at 24].

In the instant case, Plaintiff contends that the non-obviousness of the invention claimed in the '123 Patent is demonstrated by (1) the commercial success of the claimed invention, (2) the failure of others skilled in the art to solve the long standing problem of fixation, and (3) the long felt need for improved fixation of orthopedic implants. Defendants argue, on the other hand, that Plaintiff has failed to establish a nexus between the merits of the claimed invention and the secondary considerations. Instead, Defendants contend that the only relevant evidence of secondary considerations to the '123 Patent is the "contemporaneous development" of the claimed invention by the others.

1. Commercial Success

Commercial success of the claimed invention can be a strong factor favoring non-obviousness. *Simmons Fastener*, 739 F.2d at 1575-76 [222 USPQ at 746-47]. Of course, there must be a "nexus" between the merits of the claimed invention "as opposed to other commercial and economic factors unrelated to the technical quality of the patented subject matter" if evidence of commercial success is to be given substantial weight in determining the obviousness issue. *Cable Elec. Products*, 770 F.2d at 1027 [226 USPQ at 888]; *Stratoflex*, 713 F.2d at 1539 [218 USPQ at 879]. The patentee bears the burden of proving the existence of such a nexus. *Cable Elec. Products*, 770 F.2d at 1027 [226 USPQ at 888]. The Federal Circuit has established an "evidentiary routine" to be followed when a patentee asserts that

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